July 6, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket Nos. 1994P-0390 and 1995P-0241

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the May 4, 2004 Federal Register notice, "Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period," 69 Fed. Reg. 24541. FDA is reopening the comment period to its 1995 proposal to obtain input on how FDA can provide greater flexibility for manufacturers/distributors of food products who utilize nutrient content and health claims in labeling.

NNFA is a trade association representing the interests of more than 7,000 retailers, manufacturers, suppliers, and distributors of foods, dietary supplements, and other natural products throughout the United States. NNFA appreciates the opportunity to comment on the questions posed by FDA and hopes that FDA will provide for additional latitude in the use of these claims on food products.

Americans are increasingly interested in fostering their health by choosing food products that are in line with their dietary goals. In order to thoroughly and accurately convey the nutritional quality of food products, FDA should provide greater flexibility to those who make health claims. With a wider range of information being provided in food labeling, consumers gain greater access to information to help make healthier choices.

A. Section 101.14(e)(6): The Minimum Nutrient Contribution Requirement

NNFA recognizes that a minimum nutritional requirement may be necessary to ensure that food products bearing health claims have some dietary merit, and thus, takes the position that most food products bearing health claims should meet minimum nutritional standards. Currently, FDA's rules mandate that food products bearing health claims must contain 10 percent or more of the daily value ("DV") for vitamin A, vitamin C, iron, calcium, protein, or fiber, per reference amount customarily consumed ("RACC"). 21 C.F.R. § 101.14(e)(6). FDA suggests that if this requirement were revoked, another mechanism would need to be established to ensure that health claims are not made on foods with little or no nutritional value.

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Although NNFA believes that the 10 percent nutritional contribution requirement provides an acceptable minimum level for food products wishing to bear health claims, NNFA encourages FDA to consider whether all products need to meet this threshold. For instance, some products may contain ingredients that have positive health effects, but do not meet this minimum requirement (*e.g.*, herbal teas, dietary supplements, etc). If these products would otherwise qualify for a health claim, NNFA believes that the nutritional requirement should be waived. In such a case, in order to ensure that consumers have a complete understanding of the nutritional profile of the food, FDA could consider requiring such products to also bear a referral statement directing consumers to the Nutrition Facts panel, or a disclaimer regarding minimum standards.

B. Disqualifying Nutrient Levels for Health Claims

NNFA believes that FDA should provide greater flexibility in its regulations regarding disqualifying nutrient levels for health claims. Currently, a food product may not bear a health claim if it has a disqualifying level of fat, saturated fat, cholesterol, or sodium, unless the agency finds that the food is exempt from the rule because a health claim will assist consumers in constructing an overall healthy diet. 21 C.F.R. § 101.14(e)(3). An exempted food is required to bear a disclosure statement that highlights the level of the disqualifying nutrient. 21 C.F.R. § 101.13(h).

NNFA believes that FDA should more broadly permit manufacturers to use disclaimers when a food product exceeds the permitted level of fat, saturated fat, cholesterol, or sodium instead of automatically disqualifying those foods that have some nutritional value. NNFA takes this position because consumers should have access to valuable information that enables them to make informed decisions about the products they choose to eat. In a consumer survey conducted by The Natural Marketing Institute, 67.1 percent of the general population responded that they usually read food labels on food and beverage packages. Based on this strong indication of consumer interest, NNFA believes that consumers are able to competently read and understand food product labels, even if a qualifier is attached to the claim.

C. Use of "May" in Both Unqualified and Qualified Health Claims

NNFA believes that the use of the term "may" to convey two different meanings in unqualified and qualified health claims is unnecessary and confusing to consumers. While FDA has suggested that food products bearing a health claim should make clear that development of any disease depends on multiple factors, the agency did not adopt mandatory language to reflect this position. Because research showed that consumers are generally aware that disease is dependent on multiple factors, the agency decided that using the terms "may" or "might" in authorized health claims would be sufficient to suggest that diet is only one factor in preventing disease.

In its 2003 Advance Notice of Proposed Rulemaking ("ANPRM") on *qualified* health claims, however, FDA introduced the use of the term "may" to signify a lesser level of science supporting a qualified health claim. FDA now wants comment on whether it

should eliminate the use of the word "may" in unqualified health claims to avoid consumer confusion between the two uses.

NNFA believes that the multiple meaning of the term "may" in unqualified and qualified health claims is potentially confusing to consumers. Since FDA has recognized that consumers are generally aware of the multifactorial nature of disease, NNFA proposes that FDA eliminate the use of the word "may" on unqualified health claims altogether. Instead, FDA should reserve use of the term "may" to qualified health claims to indicate the lack of significant scientific agreement.

NNFA further maintains that a separate statement that conveys the multifactorial nature of disease to consumers is not necessary. As previously noted by the agency, consumers generally understand that diet is only one factor in the prevention of disease.

D. Abbreviated Health Claims

As written, FDA regulations require that all information necessary to make a truthful and not misleading health claim must appear in one place on the product label. In 21 C.F.R. § 101.14(d)(2)(iv), however, FDA does permit the use of only the name of the substance and the disease or health-related conditions, together with a reference to the complete health claim (e.g., "See attached pamphlet for information about calcium and osteoporosis"), provided the complete health claim appears at the referenced location.

In 1995, FDA introduced the concept of a true *abbreviated* health claim, provided the abbreviated statement is also accompanied by a reference statement to the complete claim. However, these abbreviated health claims are only permitted where specifically authorized by the health claim regulation. Since 1995, FDA has only authorized an abbreviated health claim for the relationship between calcium and osteoporosis.

NNFA takes the position that abbreviated health claims are a useful tool in explaining the nutritional quality of food products, while allowing greater latitude to manufacturers in communicating that message. These claims will provide an additional incentive for manufacturers to highlight healthful product characteristics in more than one place. More than half the retail stores surveyed by The Natural Marketing Institute felt that it was important for them to sell products with health claims–consumers are seeking this information. In addition, the Federal Trade Commission's Bureau of Economics found that consumers are more interested in receiving detailed information, such as that provided in the form of a health claim, than in nutrient content claims. (See, Pauline M. Ippolito and Janis K. Pappalardo, Federal Trade Commission, Advertising Nutrition & Health: Evidence from Food Advertising 1977–1997 (2002).

At the same time, NNFA believes that consumers will not be misled or misinformed about the nutritional quality of food products if these claims are used.

Consumers are able to understand that nutritional food products have an effect on their health while still understanding that these products are not a cure for all illnesses. By allowing abbreviated health claims for all authorized claims, FDA permits manufacturers to emphasize the causal relationship between nutrition and health without deceiving the public.

NNFA respectfully requests FDA to amend the existing regulations for nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products.

Respectfully submitted,

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